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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Pat. No.: 6,995,136 : Application No.: 09/673,785  
John Nelson, *et al.* : Confirmation No.: 4216  
:  
Issued: February 7, 2006 : Filed:  
:  
For: PEPTIDE FRAGMENTS OF MURINE : Attorney Docket No.  
EPIDERMAL GROWTH FACTOR AS 41934/23838  
LAMININ RECEPTOR TARGETS  
:

**REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR §1.322**  
**and 35 USC § 243**

Attention: Certificate of Corrections Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Certificate**  
**MAR 13 2006**  
**of Correction**

Sir:

Transmitted herewith is a Certificate of Correction for U.S. Pat. No. 6,995,136, issued February 7, 2006. Upon reviewing the above-identified patent, the following error was noted.

<p align="center"><b>CERTIFICATE OF MAILING</b> <b>UNDER 37 C.F.R. 1.8(a)</b></p> <p>I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Attention: Certificate of Corrections Branch, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.</p> <p>BY <u><i>Michael A. Calver</i></u> <u><i>March 7, 2006</i></u></p>
--

MAR 14 2006

**ERROR and REQUESTED CORRECTION**

Claim 12, Column 32, line 53, reads "peptide has having an N-terminal amino acid residue" which should be changed to read --peptide having an N-terminal amino acid residue--.

**REMARKS**

In the Examiner's amendment attached to the Notice of Allowance mailed July 5, 2005, claim 12, which corresponds to issued claim 12, the deletion of the word "has" in the second line of the claim was clearly indicated. See p. 3, bottom. This deletion was apparently overlooked during the printing at the United States Patent and Trademark Office. The error in claim 12, therefore, occurred through the fault of the Office. A copy of the Notice of Allowance with the Examiner's amendment is attached (Exhibit A).

Patentee respectfully solicits the granting of the requested Certificate of Correction. pursuant to 35 U.S.C. § 254. No fee is believed to be due with the filing of this paper. If any fee is required, please charge deposit account 50-0573.

Respectfully submitted,

JOHN NELSON, *ET AL.*

BY: 

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Attorney for Petitioners

**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

**Patent No.:** 6,995,136 B1

Page 1 of 1

**Application No.:** 09/673,785

**Dated:** February 7, 2006

**Inventor(s):** Nelson et al.

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below.

In Claim 12, line 53, "peptide has having an N-terminal amino acid" should read  
--peptide having an N-terminal amino acid--.

Mailing Address of Sender:  
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Substitute PTO Form 1050 (REV 3-82)

PHIP\499365\1

PATENT NO. 6,995,136  
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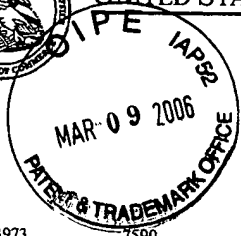
MAR 14 2006



## UNITED STATES PATENT AND TRADEMARK OFFICE

EXHIBIT A

UNITED STATES DEPARTMENT OF COMMERCE  
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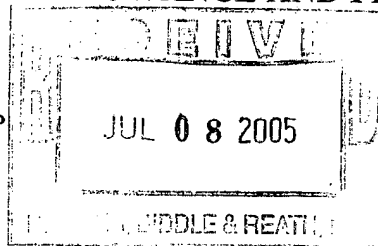
## NOTICE OF ALLOWANCE AND FEE(S) DUE

23973

7590

07/05/2005

DRINKER BIDDLE & REATH  
ATTN: INTELLECTUAL PROPERTY GROUP  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996



EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 07/05/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,785	12/29/2000	John Nelson	8830-170 181694 41934/23038	4216

TITLE OF INVENTION: PEPTIDE FRAGMENTS OF MURINE EPIDERMAL GROWTH FACTOR AS LAMININ RECEPTOR TARGETS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$0	\$1400	10/05/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. **THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.**

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

MAR 14 2006



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,785	12/29/2000	John Nelson	41934/23838	4216

23973 7590 07/05/2005  
DRINKER BIDDLE & REATH  
ATTN: INTELLECTUAL PROPERTY GROUP  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996



EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 07/05/2005

## Determination of Patent Term Extension under 35 U.S.C. 154 (b) (application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

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## Notice of Allowability

Application No.

09/673,785

Examiner

Chih-Min Kam

Applicant(s)

NELSON ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/18/05.
2. ☒ The allowed claim(s) is/are 1-10,12,14-16,18-20 and 22-27.
3. ☒ The drawings filed on 22 July 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 20050622
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Monaco on June 23, 2005.

**Examiner's Amendments to the specification:**

Please insert the following paragraph after the title at page 1:

This application is a 371 of international application PCT/GB99/01211, filed April 21, 1999, which claims the foreign priority of United Kingdom Application No. 9808407.2, filed April 21, 1998.

**Examiner's Amendments to the Claims:**

Cancel claims 13 and 17.

Claims 1, 4-7, 10, 12, 14, 15, 19, 20 and 24-26 have been amended as follows:

1. (Currently amended) A synthetic peptide factor comprising the amino acid sequence SEQ ID NO:2 wherein:
  - a) said sequence is modified such that at least one ~~or both~~ of i) SEQ ID NO:2 tyrosine amino acid residue 5 and ii) SEQ ID NO:2 arginine amino acid residue 9 are substituted, wherein said tyrosine amino acid residue 5 is substituted with a tyrosine analogue, or and said arginine amino acid residue 9 is substituted with an arginine analogue, respectively, and
  - b) the synthetic peptide factor ~~is capable of binding~~ binds to laminin receptors.
4. (Currently amended) The synthetic peptide factor of claim 1, wherein the SEQ ID NO:2 arginine residue 9 is substituted by ~~Citrulline~~ citrulline.

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5. (Currently amended) A method of antagonizing a laminin receptor in a patient, the method comprising the ~~steps~~ step of[[:]]

a) administering to the patient a medicament comprising a synthetic peptide factor comprising the amino acid sequence SEQ ID NO:2 in an amount effective to bind the laminin receptor as an antagonist, wherein said sequence is modified such that ~~at least one or both of i) SEQ ID NO:2 tyrosine amino acid residue 5 and ii) SEQ ID NO:2 arginine amino acid residue 9~~ are ~~is~~ substituted with a tyrosine analogue or an arginine analogue, ~~respectively, and~~  
b) ~~binding the synthetic peptide factor to the laminin receptor.~~

6. (Currently amended) A method of agonizing a laminin receptor in a patient, the method comprising the ~~steps~~ step of[[:]]

a) administering to the patient a medicament comprising a synthetic peptide factor comprising the amino acid sequence SEQ ID NO:2 in an amount effective to bind the laminin receptor as an agonist, wherein said sequence is modified such that ~~at least one or both of i) SEQ ID NO:2 tyrosine amino acid residue 5 and ii) SEQ ID NO:2 arginine amino acid residue 9~~ are ~~is~~ substituted with a tyrosine analogue or ~~arginine analogue, respectively, and~~  
b) ~~binding the synthetic peptide factor to the laminin receptor.~~

7. (Currently amended) The method of claim 6 wherein said medicament is for ~~treating endothelial cell wounding~~ promoting wound healing.

10. (Currently amended) The synthetic peptide factor of claim 2, wherein the SEQ ID NO:2 arginine residue 9 is substituted by ~~Citrulline~~ citrulline.

12. (Currently amended) The method of claim 5, wherein said synthetic peptide ~~has~~ having an N-terminal amino acid residue and a C-terminal amino acid residue is further



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modified, wherein the N-terminal amino acid residue is chemically modified by the addition of an amino acid capping moiety, the C-terminal amino acid residue is chemically modified by the addition of an amino acid capping moiety, or a cysteine residue thiol group is chemically modified by the addition of an amino acid capping moiety to the cysteine residue thiol group.

14. (Currently amended) The method of claim 12, wherein the SEQ ID NO:2 arginine residue 9 is substituted by ~~Citrulline~~ citrulline.

15. (Currently amended) The method of claim 6, wherein said synthetic peptide ~~has~~ having an N-terminal amino acid residue and a C-terminal amino acid residue is further modified, wherein the N-terminal amino acid residue is chemically modified by the addition of an amino acid capping moiety, the C-terminal amino acid residue is chemically modified by the addition of an amino acid capping moiety, or a cysteine residue thiol group is chemically modified by the addition of an amino acid capping moiety to the cysteine residue thiol group.

19. (Currently amended) A synthetic peptide factor comprising ~~an N-terminal amino acid residue and a C-terminal amino acid residue~~, and the amino acid sequence SEQ ID NO:2, said peptide factor having an N-terminal amino acid residue and a C-terminal amino acid residue, wherein

a) said sequence is modified by at least one first modification and optionally by at least one second modification; and

b) the synthetic peptide factor ~~is capable of binding~~ binds to laminin receptors,

wherein said first modification is selected from the group consisting of: substitution of SEQ ID NO:2 tyrosine amino acid residue 5 with a tyrosine analogue and substitution of SEQ ID NO: 2 arginine amino acid residue 9 with an arginine analogue; and

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wherein said second modification is selected from the group consisting of: chemical modification of the N-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of the C-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of a cysteine residue thiol group by the addition of an amino acid capping moiety to the cysteine residue thiol group; replacement of a peptide bond with a protease-resistant peptide bond isostere; replacement of a glycine residue with an  $\alpha,\alpha$ -dialkyl substituted amino acid; and stabilisation of a helical turn of the peptide using suitable intra chain linkers.

20. (Currently amended) A synthetic peptide factor comprising the amino acid sequence SEQ ID NO:2, and said peptide factor having an N-terminal amino acid residue and a C-terminal amino acid residue, wherein

a) said sequence is modified by ~~at least one~~ a first modification and by at least one second modification; and

b) the synthetic peptide factor ~~is capable of binding~~ binds to laminin receptors,

wherein said first modification is selected from the group consisting of: substitution of SEQ ID NO:2 tyrosine amino acid residue 5 with a tyrosine analogue and substitution of SEQ ID NO: 2 arginine amino acid residue 9 with an arginine analogue; and

wherein said second modification is selected from the group consisting of: chemical modification of the N-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of the C-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of a cysteine residue thiol group by the addition of an amino acid capping moiety to the cysteine residue thiol group; replacement of a peptide bond

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with a protease-resistant peptide bond isostere; replacement of a glycine residue with an  $\alpha,\alpha$ -dialkyl substituted amino acid; and stabilisation of a helical turn of the peptide using suitable intra chain linkers.

24. (Currently amended) A method of antagonizing a laminin receptor in a patient, the method comprising the steps step of[:]]

a) administering to the patient a medicament comprising a synthetic peptide factor in an amount effective to bind the laminin receptor as an antagonist, wherein said peptide factor comprises ~~comprising~~ the amino acid sequence SEQ ID NO:2, and said peptide factor having an N-terminal amino acid residue and a C-terminal amino acid residue;

wherein said sequence is modified by ~~at least one~~ a first modification and optionally by at least one second modification;

wherein said first modification is ~~selected from the group consisting of: substitution of SEQ ID NO:2 tyrosine amino acid residue 5 with a tyrosine analogue and substitution of arginine amino acid residue 9 with an arginine analogue; and~~

wherein said second modification is selected from the group consisting of: chemical modification of the N-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of the C-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of a cysteine residue thiol group by the addition of an amino acid capping moiety to the cysteine residue thiol group; replacement of a peptide bond with a protease-resistant peptide bond isostere; replacement of a glycine residue with an  $\alpha,\alpha$ -dialkyl substituted amino acid; and stabilization of a helical turn of the peptide using suitable intra chain linkers; ~~and~~

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~~b) binding the synthetic peptide factor to the laminin receptor.~~

25. (Currently amended) A method of agonizing a laminin receptor in a patient, the method comprising the steps step of of[[:]]

a) administering to the patient a medicament comprising a synthetic peptide factor in an amount effective to bind the laminin receptor as an agonist, wherein said peptide factor comprises ~~comprising~~ the amino acid sequence SEO ID NO:2, and said peptide factor having an N-terminal amino acid residue and a C-terminal amino acid residue;

wherein said sequence is modified by ~~at least one~~ a first modification and optionally by at least one second modification;

wherein said first modification is ~~selected from the group consisting of:~~ substitution of SEQ ID NO:2 tyrosine amino acid residue 5 with a tyrosine analogue and ~~substitution of arginine amino acid residue 9 with an arginine analogue;~~ and

wherein said second modification is selected from the group consisting of: chemical modification of the N-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of the C-terminal amino acid residue by the addition of an amino acid capping moiety; chemical modification of a cysteine residue thiol group by the addition of an amino acid capping moiety to the cysteine residue thiol group; replacement of a peptide bond with a protease-resistant peptide bond isostere; replacement of a glycine residue with an  $\alpha,\alpha$ -dialkyl substituted amino acid; and stabilisation of a helical turn of the peptide using suitable intra chain linkers; ~~and~~

~~b) binding the synthetic peptide factor to the laminin receptor.~~

10/14/2006

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26. (Currently amended) The method of claim 25 wherein said medicament is for treating endothelial cell wounding promoting wound healing.

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be related to the claimed invention. Nelson *et al.* (J. Biol. Chem. 271, 26179-26186 (1996)) teach a laminin-antagonist peptide with amino acid residues 33-42 of mEGF interacts with a 67 kDa laminin receptor of breast cancer and endothelial cell. However, the reference does not teach or suggest a synthetic peptide factor comprising the amino acid sequence SEQ ID NO:2 (CVIGYSGDRC), wherein the sequence is modified and has at least one of SEQ ID NO:2 tyrosine amino acid residue 5 being substituted with a tyrosine analogue and SEQ ID NO:2 arginine amino acid residue 9 being substituted with an arginine analogue. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

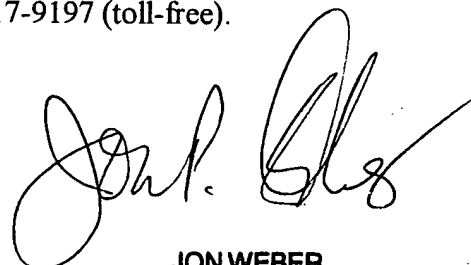
Chih-Min Kam, Ph. D.

CMK

Patent Examiner

CMK

June 23, 2005



JON WEBER

ADVISORY PATENT EXAMINER

JUN 23 2005